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**Phase 2 Safety and Efficacy Study of CLBS03 Autologous T-Regulatory Cells in Adolescents with Recent Onset Type 1 Diabetes Mellitus**

**Grant Award Details**

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Phase 2 Safety and Efficacy Study of CLBS03 Autologous T-Regulatory Cells in Adolescents with Recent Onset Type 1 Diabetes Mellitus

**Grant Type:** Clinical Trial Stage Projects

**Grant Number:** CLIN2-09730

**Project Objective:** Phase II Trial completed

**Investigator:**

<b>Name:</b>	Douglas Losordo
<b>Institution:</b>	Caladrius Biosciences
<b>Type:</b>	PI

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**Disease Focus:** Diabetes, Type 1 diabetes

**Award Value:** \$12,211,255

**Status:** Active

**Grant Application Details**

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**Application Title:** Phase 2 Safety and Efficacy Study of CLBS03 Autologous T-Regulatory Cells in Adolescents with Recent Onset Type 1 Diabetes Mellitus

**Public Abstract:****Therapeutic Candidate or Device**

Autologous Ex Vivo Expanded Polyclonal CD4<sup>+</sup>CD25<sup>+</sup>CD127<sup>lo</sup>/<sup>-</sup>FOXP3<sup>+</sup> Regulatory T-cells (CLBS03)

**Indication**

Early Onset Type 1 Diabetes Mellitus with Residual Beta Cell Function

**Therapeutic Mechanism**

It must be acknowledged that the mechanism(s) by which the effector arm of the immune system becomes unrestrained in the setting of T1D, resulting in the immune destruction of pancreatic beta-islet cells, is not known at this time. Available evidence indicates that Tregs maintain immune balance by modulating multiple facets of the effector arm of the immune system at least in part by control of differentiation of multipotent progenitor/stem cells.

**Unmet Medical Need**

No therapy aimed at maintaining or restoring pancreatic beta islet cell function is currently approved for Type 1 diabetes mellitus (T1D). As a result children with T1D face lifelong struggles with glycemic control and, despite careful management, an increased risk of severe complications.

**Project Objective**

Phase 2 trial completed

**Major Proposed Activities**

- Enrollment and treatment of the remaining 92 subjects in the phase 2 clinical trial
- Manufacturing investigational product for the remaining subjects in the trial

**Statement of Benefit to California:**

All cell manufacturing for this study will be performed in California. Accordingly this project will have an immediate positive effect on employment of highly skilled workers in California. The demonstration of preservation of beta-islet cell function, with attendant reductions in exogenous insulin requirements, would provide compelling clinical evidence to advance this therapy and would provide strong momentum toward advancing a cure of T1D. Such a cure would benefit California and the world.

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